

AMENDED IN SENATE MARCH 11, 2014  
AMENDED IN SENATE JANUARY 7, 2014  
AMENDED IN SENATE SEPTEMBER 6, 2013  
AMENDED IN SENATE AUGUST 19, 2013  
AMENDED IN SENATE AUGUST 12, 2013  
AMENDED IN ASSEMBLY APRIL 11, 2013  
AMENDED IN ASSEMBLY MARCH 19, 2013

CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

## **ASSEMBLY BILL**

**No. 467**

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**Introduced by Assembly Member Stone**  
(Principal coauthor: Senator Hill)

February 19, 2013

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An act to add Section 4046 to, and to add Article 11.5 (commencing with Section 4169.5) to Chapter 9 of Division 2 of, the Business and Professions Code, and to amend Sections 150201, 150202, and 150205 of, and to add Section 150208 to, the Health and Safety Code, relating to pharmaceuticals, making an appropriation therefor, and declaring the urgency thereof, to take effect immediately.

### LEGISLATIVE COUNSEL'S DIGEST

AB 467, as amended, Stone. Prescription drugs: collection and distribution program.

Existing law authorizes a county to establish, by ordinance, a repository and distribution program under which specified pharmacies and primary care clinics may distribute surplus unused medications, as

defined, to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. Existing law authorizes specified health and care facilities, pharmacies, drug manufacturers, and pharmacy wholesalers to donate unused medications to the program. Existing law requires a county that has established a program to establish procedures to, among other things, ensure proper safety and management of any medications collected and maintained by a participating entity. Existing law exempts specified persons and entities, including prescription drug manufacturers and pharmacists and physicians who accept or dispense prescription drugs, from criminal and civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with these provisions.

Existing law, the Pharmacy Law, governs the scope and practice of pharmacy, including dispensing dangerous drugs and devices. Existing law establishes in the Department of Consumer Affairs the California State Board of Pharmacy to exercise licensing, regulatory, and disciplinary functions with respect to the practice of pharmacy. Existing law provides that fees collected on behalf of the board are credited to the Pharmacy Board Contingent Fund, a continuously appropriated fund. A violation of the Pharmacy Law is a crime.

This bill would require the California State Board of Pharmacy to license a surplus medication collection and distribution intermediary, as defined, established for the purpose of facilitating the donation of medications to or transfer of medications between participating entities under the unused medication repository and distribution program described above. Among other things, the bill would prohibit that intermediary from taking possession, custody, or control of dangerous drugs and devices, but would authorize the intermediary to charge specified fees for the reasonable costs of the support and services provided. The bill would also require a surplus medication collection and distribution intermediary to keep and maintain for 3 years complete records for which the intermediary facilitated the donation of medications to or transfer of medications between participating entities. The bill would require that a surplus medication collection and distribution intermediary ~~be licensed by the board, as specified, would require that the~~ license be renewed annually, and would require the payment of a fee in the amount of \$300 to obtain or renew the license. The bill would provide that the fees collected would be deposited in the Pharmacy Board Contingent Fund. By providing a new source of funds for a continuously appropriated fund, the bill would make an

appropriation. Because a violation of the provisions governing licensing and ~~record-keeping~~ *recordkeeping* would be crimes, the bill would impose a state-mandated local program. The bill would exempt a surplus medication collection and distribution intermediary from criminal or civil liability for injury caused when facilitating the donation of medications to or transfer of medications in compliance with these provisions.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

This bill would declare that it is to take effect immediately as an urgency statute.

Vote:  $\frac{2}{3}$ . Appropriation: yes. Fiscal committee: yes.  
State-mandated local program: yes.

*The people of the State of California do enact as follows:*

1 SECTION 1. Section 4046 is added to the Business and  
2 Professions Code, to read:

3 4046. "Surplus medication collection and distribution  
4 intermediary" means a firm, association, partnership, corporation,  
5 limited liability company, state governmental agency, or political  
6 subdivision that performs the functions specified in Section 4169.5  
7 for the purpose of a program established pursuant to Division 116  
8 (commencing with Section 150200) of the Health and Safety Code.

9 SEC. 2. Article 11.5 (commencing with Section 4169.5) is  
10 added to Chapter 9 of Division 2 of the Business and Professions  
11 Code, to read:

12  
13 Article 11.5. Surplus Medication Collection and Distribution  
14 Intermediaries  
15

16 4169.5. (a) A surplus medication collection and distribution  
17 intermediary established for the purpose of facilitating the donation  
18 of medications to or transfer of medications between participating  
19 entities under a program established pursuant to Division 116  
20 (commencing with Section 150200) of the Health and Safety Code  
21 shall be licensed by the board. The board shall enforce the

1 requirements set forth in Section 150208 of the Health and Safety  
2 Code. The license shall be renewed annually.

3 (b) An application for licensure as a surplus medication  
4 collection and distribution intermediary shall be made on a form  
5 furnished by the board, and shall state the name, address, usual  
6 occupation, and professional qualifications, if any, of the applicant.  
7 If the applicant is an entity other than a natural person, the  
8 application shall state the information as to each person beneficially  
9 interested in that entity.

10 (c) As used in this section, and subject to subdivision (e), the  
11 term “person beneficially interested” means and includes:

12 (1) If the applicant is a partnership or other unincorporated  
13 association, each partner or member.

14 (2) If the applicant is a corporation, each of its officers, directors,  
15 and stockholders, provided that no natural person shall be deemed  
16 to be beneficially interested in a nonprofit corporation.

17 (3) If the applicant is a limited liability company, each officer,  
18 manager, or member.

19 (d) If the applicant is a charitable organization described in  
20 Section 501(c)(3) of the Internal Revenue Code, the applicant shall  
21 furnish the board with the organization’s articles of incorporation.  
22 The applicant shall also furnish the board with the names of the  
23 controlling members.

24 (e) If the applicant is a partnership or other unincorporated  
25 association, a limited liability company, or a corporation, and if  
26 the number of partners, members, or stockholders, as the case may  
27 be, exceeds five, the application shall so state, and shall further  
28 state the information required by subdivision ~~(a)~~ (b) as to each of  
29 the five partners, members, or stockholders who own the five  
30 largest interests in the applicant’s entity. Upon request by the  
31 executive officer of the board, the applicant shall furnish the board  
32 with the information required by subdivision ~~(a)~~ (b) as to partners,  
33 members, or stockholders not named in the application, or shall  
34 refer the board to an appropriate source of that information.

35 (f) The application shall contain a statement to the effect that  
36 the applicant or persons beneficially interested have not been  
37 convicted of a felony and have not violated any of the provisions  
38 of this chapter. If the applicant cannot make this statement, the  
39 application shall contain a statement of the violation, if any, or

1 reasons which will prevent the applicant from being able to comply  
2 with the requirements with respect to the statement.

3 (g) Upon the approval of the application by the board and  
4 payment of a fee in the amount of three hundred dollars (\$300),  
5 the executive officer of the board shall issue or renew a license to  
6 operate as a surplus medication collection and distribution  
7 intermediary, if all of the provisions of this chapter have been  
8 complied with. Fees received by the board pursuant to this section  
9 shall be deposited into the Pharmacy Board Contingent Fund. An  
10 applicant for licensure as a surplus medication collection and  
11 distribution intermediary that is government owned or is a nonprofit  
12 organization pursuant to subdivision (d) is exempt from the fee  
13 requirement.

14 (h) A surplus medication collection and distribution intermediary  
15 licensed pursuant to this section is exempt from licensure as a  
16 wholesaler.

17 (i) A surplus medication collection and distribution intermediary  
18 licensed pursuant to this section shall keep and maintain for three  
19 years complete records for which the intermediary facilitated the  
20 donation of medications to or transfer of medications between  
21 participating entities.

22 SEC. 3. Section 150201 of the Health and Safety Code is  
23 amended to read:

24 150201. For purposes of this division:

25 (a) "Donor organization" means an entity described in  
26 subdivision (a) of Section 150202.

27 (b) "Eligible entity" means all of the following:

28 (1) A licensed pharmacy, as defined in subdivision (a) of Section  
29 4037 of the Business and Professions Code, that is county owned  
30 or that contracts with the county pursuant to this division and is  
31 not on probation with the California State Board of Pharmacy.

32 (2) A licensed pharmacy, as defined in subdivision (a) of Section  
33 4037 of the Business and Professions Code, that is owned and  
34 operated by a primary care clinic, as defined in Section 1204, that  
35 is licensed by the State Department of Public Health and is not on  
36 probation with the California State Board of Pharmacy.

37 (3) A primary care clinic, as defined in Section 1204, that is  
38 licensed by the State Department of Public Health and licensed to  
39 administer and dispense drugs pursuant to subparagraph (A) of  
40 paragraph (1) of subdivision (a) of Section 4180 of the Business

1 and Professions Code and is not on probation with the California  
2 State Board of Pharmacy.

3 (c) “Medication” or “medications” means a dangerous drug, as  
4 defined in Section 4022 of the Business and Professions Code.

5 (d) “Participating entity” means an eligible entity that has  
6 received written or electronic documentation from the county  
7 health department pursuant to paragraph (3) of subdivision (a) of  
8 Section 150204 and that operates a repository and distribution  
9 program pursuant to this division.

10 SEC. 4. Section 150202 of the Health and Safety Code is  
11 amended to read:

12 150202. (a) Notwithstanding any other law, a donor  
13 organization is defined, for purposes of this division, to refer to  
14 one of the following health and care facilities that may donate  
15 centrally stored unused medications under a program established  
16 pursuant to this division:

17 (1) A licensed general acute care hospital, as defined in Section  
18 1250.

19 (2) A licensed acute psychiatric hospital, as defined in Section  
20 1250.

21 (3) A licensed skilled nursing facility, as defined in Section  
22 1250, including a skilled nursing facility designated as an  
23 institution for mental disease.

24 (4) A licensed intermediate care facility, as defined in Section  
25 1250.

26 (5) A licensed intermediate care facility/developmentally  
27 disabled-habilitative facility, as defined in Section 1250.

28 (6) A licensed intermediate care facility/developmentally  
29 disabled-nursing facility, as defined in Section 1250.

30 (7) A licensed correctional treatment center, as defined in  
31 Section 1250.

32 (8) A licensed psychiatric health facility, as defined in Section  
33 1250.2.

34 (9) A licensed chemical dependency recovery hospital, as  
35 defined in Section 1250.3.

36 (10) A licensed residential care facility for the elderly, as defined  
37 in Section 1569.2, with 16 or more residents.

38 (11) An approved mental health rehabilitation center, as  
39 described in Section 5675 of the Welfare and Institutions Code.

1 (b) Medication donated by health and care facilities pursuant  
2 to subdivision (a) shall meet the requirements of subdivisions (c)  
3 and (d) of Section 150204 and shall be unexpired medication that  
4 would have otherwise been destroyed by the facility or another  
5 appropriate entity.

6 (c) Medication eligible for donation by the health and care  
7 facilities pursuant to subdivision (a) shall be directly delivered  
8 from the dispensing pharmacy, wholesaler or manufacturer, to the  
9 health or care facility and subsequently centrally stored. Centrally  
10 stored medication that originated from a patient or resident is not  
11 eligible for donation under this division.

12 SEC. 5. Section 150205 of the Health and Safety Code is  
13 amended to read:

14 150205. (a) The following persons and entities shall not be  
15 subject to criminal or civil liability for injury caused when  
16 donating, accepting, or dispensing prescription drugs in compliance  
17 with this division:

18 (1) A prescription drug manufacturer, wholesaler, governmental  
19 entity, or participating entity.

20 (2) A pharmacist or physician who accepts or dispenses  
21 prescription drugs.

22 (3) A licensed health or care facility, as described in Section  
23 150202, or a pharmacy, as described in Section 150202.5.

24 (b) A surplus medication collection and distribution  
25 intermediary, as described in Section 150208, shall not be subject  
26 to criminal or civil liability for injury caused when facilitating the  
27 donation of medications to or transfer of medications in compliance  
28 with this division.

29 SEC. 6. Section 150208 is added to the Health and Safety Code,  
30 to read:

31 150208. (a) A surplus medication collection and distribution  
32 intermediary that is licensed pursuant to Section 4169.5 of the  
33 Business and Professions Code, established for the purpose of  
34 facilitating the donation of medications to or transfer of  
35 medications between participating entities under a program  
36 established pursuant to this division is authorized to operate under  
37 this section.

38 (b) A surplus medication collection and distribution intermediary  
39 shall comply with the following:

1 (1) It shall not take possession, custody, or control of dangerous  
2 drugs and devices.

3 (2) It shall ensure that notification is provided to participating  
4 entities that a package has been shipped when the surplus  
5 medication collection and distribution intermediary has knowledge  
6 of the shipment and provided logistical support to facilitate a  
7 shipment directly from a donor organization, as defined in  
8 subdivision (a) of Section 150202, to a participating entity.

9 (3) It shall not select, or direct a donor organization, as defined  
10 in subdivision (a) of Section 150202, to select, a specific  
11 participating entity to receive surplus medications.

12 (c) A surplus medication collection and distribution intermediary  
13 is authorized to do the following:

14 (1) Charge membership, administrative, or overhead fees  
15 sufficient to cover the reasonable costs of the support and services  
16 provided.

17 (2) Contract directly with a county to facilitate the donation of  
18 medications to or transfer of medications between participating  
19 entities and provide general support in a county's implementation  
20 of a program established pursuant to this division.

21 (d) No participating entities shall receive donated medication  
22 directly from the surplus medication collection and distribution  
23 intermediary.

24 SEC. 7. No reimbursement is required by this act pursuant to  
25 Section 6 of Article XIII B of the California Constitution because  
26 the only costs that may be incurred by a local agency or school  
27 district will be incurred because this act creates a new crime or  
28 infraction, eliminates a crime or infraction, or changes the penalty  
29 for a crime or infraction, within the meaning of Section 17556 of  
30 the Government Code, or changes the definition of a crime within  
31 the meaning of Section 6 of Article XIII B of the California  
32 Constitution.

33 SEC. 8. This act is an urgency statute necessary for the  
34 immediate preservation of the public peace, health, or safety within  
35 the meaning of Article IV of the Constitution and shall go into  
36 immediate effect. The facts constituting the necessity are:

37 To ensure that California's medication donation program is  
38 allowed to continue to operate to facilitate the distribution of  
39 medications to the indigent population which would not otherwise



- 1 have access to these medications, it is necessary that this act take
- 2 effect immediately.

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